

NIH trial to track outcomes of liver transplantation from HIV+ donors to HIV+ recipients

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Close up of two red AIDS awareness ribbons pinned to white fabric. Credit: NIAID

The first large-scale clinical trial to study liver transplantation between people with HIV has begun at clinical centers across the United States. The HOPE in Action Multicenter Liver Study will determine the safety of this practice by evaluating liver recipients for potential transplant-related and HIV-related complications following surgery. The study is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and follows the 2018 launch of a similar study evaluating kidney transplantation between people with HIV.

While [organ transplants](#) between donors and recipients with HIV have been successfully completed in South Africa since 2008, such transplants were illegal in the United States until the passage of the HIV Organ Policy Equity (HOPE) Act in 2013. The HOPE Act permits U.S. transplant teams with an approved research

protocol to transplant organs from donors with HIV to qualified recipients with HIV and [end-stage organ failure](#), a practice that may shorten the time they have to wait to receive a transplant. The transplantation of organs from donors with HIV to HIV-negative recipients remains illegal in the United States.

Individuals with HIV have a higher risk of end-stage [liver](#) and kidney diseases because of damage caused by the virus and by common coinfections and associated comorbidities, such as hepatitis B and C viruses, hypertension and diabetes mellitus. Certain antiretroviral treatments also can cause toxicities that damage these organs.

In the early decades of the HIV/AIDS pandemic, individuals were rarely eligible to receive organ transplants from HIV-negative donors; these organs are consistently in short supply and high demand, because health outcomes were projected to be poor. However, NIAID-sponsored studies demonstrated that by carefully selecting individuals with HIV who are otherwise healthy to receive a kidney or liver from an HIV-negative [donor](#), patient and organ graft survival rates could be like those of transplant HIV-negative recipients. These findings provided the scientific basis for the eventual passage of the HOPE Act of 2013.

"Antiretroviral therapy has been incredibly successful in helping people with HIV live longer, healthy lives. As more people with HIV grow older, we see organ damage in this population linked to age, HIV and other infections," said NIAID Director Anthony S. Fauci, M.D. "The HOPE in Action Multicenter Liver Study will allow researchers to evaluate the safety and efficacy of transplanting livers from donors with HIV to HIV-positive recipients. This strategy has the potential to both improve the wellbeing of those with HIV and

increase the overall supply of transplantable livers."

The trial team previously launched the HOPE in Action Multicenter Kidney Study in May 2018, which is evaluating the safety and efficacy of [kidney transplantation](#) between people with HIV. At its launch, this trial was the first study of its type in the United States to receive Institutional Review Board (IRB) approval by following the research criteria and guidance mandated by the HOPE Act of 2013.

The new study will track the clinical outcomes of 80 liver transplants. All transplant recipients in the study will be living with HIV; 40 of them will receive livers from deceased donors who had HIV, and 40 will receive livers from HIV-negative deceased donors serving as the control group. About 8 percent of people waiting for a liver transplant also require a simultaneous kidney transplant, and these recipients are also eligible to receive both organs from a single deceased donor. Individuals with hepatitis C virus (HCV) can receive organ transplants from donors with HCV. Health care teams and study participants will be made aware of the HIV and HCV status of the organ donor and will be counseled on HCV treatment.

"Liver transplants are the second most common type of organ transplant performed in the United States, and the number of people waiting for these life-saving procedures—both with and without HIV—increases every year," said Christine Durand, M.D., associate professor of medicine at Johns Hopkins University and principal investigator of the HOPE in Action Multicenter Liver Study. "Should liver transplants between people with HIV be shown to be safe and effective through this research, the donor pool will expand—saving lives and reducing the time that both HIV-negative and HIV-positive people spend on an organ transplant waiting list."

Throughout the clinical trial, researchers will monitor the liver transplant recipients closely for signs of organ rejection, organ failure, failure of previously effective anti-HIV medications and HIV-associated complications. The HOPE in Action team will compare the results of those recipients who received livers from donors with HIV to those who received livers from HIV-negative donors. Researchers will also track participants'

psychological and social responses, changes in their reservoirs of latent HIV, and the potential development of HIV superinfection, a condition of infection with more than one strain of HIV.

"Liver transplantation has a proven track record of saving and improving lives," said Jonah Odum, M.D., Ph.D., Chief of the Clinical Transplantation Section in NIAID's Division of Allergy, Immunology and Transplantation. "The HOPE in Action team—with the collaboration of the Organ Procurement and Transplantation Network, regional organ procurement organizations and the major transplantation centers participating in the trial—is doing the important work of determining if transplants can provide equal benefit when the liver comes from a person with HIV."

The study will comply with all current federal laws surrounding organ procurement and transplantation and meet the HOPE Act Safeguards and Research Criteria as set forth by the U.S. Department of Health and Human Services in a 2015 [Federal Register](#) notice. These safeguards, developed for HHS with NIAID's leadership, include organ recipients discussing the study with an independent advocate prior to transplantation. Additionally, participating organ recipients must be in good immune health and on effective antiretroviral therapy. Recipients must also be willing to adhere to [transplant](#) and anti-HIV—related medications. Individuals with HIV interested in registering their decision to be deceased organ donors can learn more at [OrganDonor.gov](#).

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For more information about the HOPE in Action Multicenter Liver study, please visit [ClinicalTrials.gov](#) under study identifier [NCT03734393](#). For more information about the HOPE in Action Multicenter Kidney Study, please visit [ClinicalTrials.gov](#) under study identifier [NCT03500315](#).

Provided by NIH/National Institute of Allergy and

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